UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

In re: Bair Hugger Forced Air Warming Devices Products Liability Litigation	MDL No. 15-2666 (JNE/DTS)
This Document Relates To: ALL ACTIONS	**DEFENDANTS' OPPOSITION TO PLAINTIFFS' MOTION TO COMPEL DEFENDANTS TO SUPPLEMENT DISCOVERY RESPONSES**

The Court bifurcated general causation and case-specific discovery, and fact discovery on general causation closed on March 20, 2017. Dkt. No. 175, Pretrial Order No. 17. Last year, Plaintiffs attempted to unilaterally reopen general causation discovery by "supplementing" and disclosing new expert reports. This Court concluded that Plaintiffs violated the scheduling order and excluded those new expert reports pursuant to Rules 16 and 37. Dkt. No. 1580, Order, affirming Dkt. No. 1522.[1] Plaintiffs' latest motion comes at the same issue from a different direction: Plaintiffs argue now that Defendants violated their discovery obligations by *failing* to unilaterally reopen general causation discovery, but Plaintiffs make that argument under the guise of supplementation. Plaintiffs are wrong about Defendants' discovery obligations, both with respect to the specific topics they raise and their broad push for general causation discovery to be reopened. Defendants have

[1] Plaintiffs have repeatedly ignored the general causation discovery deadline. The Court twice quashed Plaintiffs' unauthorized subpoena to a third-party witness, noting that "the time for fact discovery has closed." Dkt. No. 1322, Order at 2; *see also* Dkt. No. 1168, Order at 1.

satisfied their supplementation obligations under the Federal Rules. Their motion should be denied.

Fed. R. Civ. P. 26(e)(1) provides that a party has a duty to supplement in a timely manner "if the party learns that in some material respect the disclosure or response is incomplete or incorrect, and if the additional or corrective information has not otherwise been made known to the other parties during the discovery process or in writing." With respect to the three specific subjects of discovery identified in Plaintiffs' Memorandum (communications with the FDA leading up to the FDA's August 2017 letter, the 2018 International Consensus Meeting, and the "RIIiO" pilot study in the United Kingdom), 3M's discovery responses on these issues are not incomplete or incorrect in any material respect. Plaintiffs do not (and cannot) demonstrate otherwise. Plaintiffs concede that Defendants produced the FDA communications at issue. The sponsors and delegates of the 2018 International Consensus Meeting on Musculoskeletal (ICM), as well as the authors, editors, and findings of the ICM's published report, are a matter of public record and known to Plaintiffs. The RIIiO pilot study, which being conducted by independent researchers in the UK and partially funded by 3M, is still ongoing and has not announced any results. Accordingly, neither party is relying on it and it is, at least presently, irrelevant to the litigation.[2]

[2] Twenty-three of the 28 pages of Plaintiffs' Memorandum are devoted to a recitation of Plaintiffs' favorite documents and testimony, as a purported "reminder about some of the key allegations involved in this MDL." Pls.' Mem. at 2. As the Court is aware, Defendants strongly dispute those allegations. Because, however, the first 23 pages do not appear to be relevant to the relief sought by Plaintiffs, Defendants focus their response on the remaining 5 pages. In any event, the Court has reviewed and addressed these allegations and

Plaintiffs' broader request, raised in a footnote – that Defendants be ordered to comprehensively refresh their document production in response to Plaintiffs' hundreds of general causation discovery requests – finds no support in the Federal Rules or the case law. The duty to supplement under Rule 26(e)(1)(A), which Defendants have satisfied, is a limited duty, requiring a party to supplement only to correct material errors or incompleteness. The duty is further limited by Rule 26(b)(1), which confines discovery to materials relevant to the parties' claims and defenses, and seeks to avoid imposing disproportionate burdens. *See, e.g.*, *Progressive Cas. Ins. Co. v. F.D.I.C.*, 302 F.R.D. 497, 504 (N.D. Iowa 2014) (denying motion to compel supplementation because the defendant "has not shown that [the plaintiff] is withholding responsive, discoverable materials concerning" defendant's discovery requests). Moreover, a broad demand to reopen general causation fact discovery must be supported by good cause under Rule 16(b)(4), and Plaintiffs have failed to show good cause here.

In considering Plaintiffs' motion, the Court should also consider Plaintiffs' fulfillment of their own general causation discovery obligations. In October 2016, Judge Noel advised the parties that all Plaintiffs' firms (not just the leadership) must separately answer certain of Defendants' interrogatories and discovery requests for their cases in the MDL. Dkt. No. 121, Court Minutes. To this day, 40 Plaintiffs' firms still have never complied with that requirement, and no Plaintiffs' firm has ever supplemented its responses

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documents in its order denying Plaintiffs' motion for leave to seek punitive damages and granting Defendants' motion for summary judgment on failure-to-warn- and fraud-based claims in *Gareis*.

since the close of general causation discovery. Decl. of Benjamin W. Hulse ¶ 2. Even if the Court were to reopen general causation discovery on some limited basis – and it should not – the first order of business should be addressing Plaintiffs' failure to fulfill their own discovery duties.

ARGUMENT

I. DEFENDANTS' PRODUCTION ON THE TOPICS IDENTIFIED BY PLAINTIFFS IS NOT MATERIALLY INCOMPLETE OR INCORRECT SUCH THAT THERE IS A DUTY TO SUPPLEMENT.

Since the close of general causation fact discovery on March 20, 2017, Defendants have fulfilled their obligation under Rule 26(e)(1) to supplement where warranted. Defendants made supplemental general-causation document productions on March 27, 2017; March 31, 2017; April 17, 2017; May 3, 2017; June 7, 2017; June 22, 2017; July 14, 2017; August 1, 2017; and November 7, 2017. Hulse Decl. ¶ 1. By contrast, Plaintiffs have never supplemented their general-causation document production. *Id.* ¶ 3.

Plaintiffs identify three areas where they contend Defendants should supplement their discovery: (i) communications with the FDA leading up to the August 2017 letter; (ii) documents relating to the 2018 International Consensus on Prevention of Periprosthetic Joint Infection; and (iii) documents relating to an ongoing pilot study in the United Kingdom (the "RIIiO" pilot study). Defendants' production is not materially incomplete or incorrect for any of these three subjects.

B. FDA Communications Prior to August 2017 Letter.

The Court should deny Plaintiffs' request that Defendants be ordered to supplement their production of communications with the FDA leading up to the FDA's August 30, 2017 letter. Defendants' production is complete.

In response to the misinformation being spread by Plaintiffs and their ally, Dr. Augustine, the FDA advised healthcare providers in that letter that it "has been unable to identify a consistently reported association between the use of forced air thermal regulating systems and surgical site infection." (www.fda.gov/medicaldevices/safety/letterstohealthcareproviders/ucm573837.htm.) Without support, Plaintiffs characterize the FDA's letter as the results of a "lobbying campaign" by 3M, but the FDA made clear that it was not – it conducted a comprehensive, independent investigation and considered many sources of information. (*Id.*) Plaintiffs ignore the FDA's own statement on the issue. In the FDA's words, it "collected and analyzed data available to date from several sources, including medical device reports received by the agency, information from manufacturers and hospitals, publically available medical literature, operating rooms guidelines, and ventilation requirements." (*Id.*)

Plaintiffs' complaint about Defendants' production of FDA communications lacks support, for two reasons.

First, Plaintiffs concede that Defendants produced their communications with the FDA. Pls.' Mem. at 24. Plaintiffs complain that Defendants made the production on November 17, 2017, after the hearing on the parties' *Daubert* motions. But the letter was not even issued until August 30, 2017, and Plaintiffs did not serve their supplemental

discovery requests until mid-September. (Though these requests were served without leave after the close of general causation discovery, Defendants consented to answer them given the clear relevance.) It is also difficult to see how the date of the production prejudiced Plaintiffs. Following the production, Plaintiffs did not make any supplemental submission to the Court, and the Court ultimately denied Defendants' *Daubert* and summary judgment motions on December 13, 2017.

Second, further discovery would not lead to the discovery of evidence that would be admissible at trial under the Court's evidentiary rulings. The Court excluded the FDA's letter in the *Gareis* trial on Plaintiffs' motion. While the Court excluded the letter under Fed. R. Evid. 403, rather than Fed. R. Evid. 402, the fact remains that the Court deemed the letter inadmissible. Even if the FDA letter is admitted into evidence in a future bellwether trial, further discovery should still not be permitted because (as discussed above), Defendants have fulfilled their discovery obligations.

At bottom, Plaintiffs offer no evidence that Defendants' production was incomplete or incorrect, and Defendants are not aware of any. Their request should be denied.[3]

C. 2018 International Consensus Meeting.

Next, Plaintiffs argue that Defendants should supplement their production to produce documents relating to the 2018 International Consensus Meeting. Again, Defendants are unaware of any way in which their production is materially incomplete or incorrect, and Plaintiffs fail to identify any.

[3] Plaintiffs themselves have never supplemented their own production with any communications they had with the FDA, either before or after the FDA issued the letter.

The ICM findings and proceedings are a matter of public record. *See* Fed. R. Civ. P. 26(e)(1)(A) (a party is not under a duty to supplement information that has "otherwise been made known to the other parties during the discovery process or in writing"). The ICM met in July 2018 and published the report of its consensus statements online on November 12, 2018 (https://icmphilly.com/2018/11/). The ICM notes that its statements were "compiled as the result of work of over 800 individuals from around the globe," including delegates from all subspecialties of orthopedics. Of particular significance to this litigation, the delegates considered the same scientific studies upon which Plaintiffs relied in their Master Complaint and at the *Gareis* trial and concluded: "There is no evidence to definitely link FAW [forced air warming] to an increased risk of SSIs/PJIS [surgical site infections/periprosthetic joint infections]." The delegates reached what the ICM terms a "strong consensus." Ninety-three percent of the participating delegates voted in support of the consensus statement, while only 2 percent voted against. A supporting statement of the ICM's rationale was co-authored by Dr. Mike Reed, the senior author of the 2011 McGovern study (the study that is the centerpiece of Plaintiffs' case). The statement of rationale concludes:

- "Maintaining intraoperative normothermia has been shown to reduce perioperative complications including SSI. FAW represents one of the most widely-used methods to prevent hypothermia and maintain intraoperative normothermia."

- "In conclusion, the literature is conflicting and there is still a lack of strong evidence linking FAW to increased risk of SSI. In light of this, while we recognize the theoretical risk posed by FAW, we cannot recommend discontinuing the use of these devices at this time."

Hulse Decl. Ex. A at 112-14. Dr. Mike Reed, the senior author of the McGovern study, is one of the three listed co-authors of the ICM's statement of rationale.

The ICM delegates also reached a "strongest consensus" (97 percent agree, 1 percent disagree) recommending that normothermia be maintained in patients undergoing orthopedic procedures. *Id.* at 115. The supporting statement of rationale concludes: "There are no studies which provide high-level evidence that warming systems may increase infection rates." *Id.* at 116.

Defendants agree that the ICM's conclusions – which reject Plaintiffs' theory of causation – are relevant to this litigation. However, Plaintiffs have never articulated what ICM-related documents (apart from the report, which is readily available online) they believe Defendants have and should produce, much less why such documents would be relevant to their claims. Plaintiffs did not meet and confer on the issue before filing their motion, and their Memorandum does not specify any types of documents or specific subjects of discovery.

The identities of the sponsors and delegates are public. 3M's sponsorship of the ICM is disclosed on page ix of the ICM's report. Hulse Decl. Ex. B. It is also disclosed that Dr. Michael Mont, one of 3M's retained experts in the *Gareis* trial, was one of the 800 delegates and one of the editors of the published compilation of consensus statements. Likewise, the report discloses that Mike Reed, the senior author of the McGovern study, was a delegate and co-author. *Id.* at xix; Ex. A at 112. Thus, the points that either side might wish to make about who was involved in the ICM, and who sponsored it, do not require any further discovery.

For these reasons, Plaintiffs' vague request that the Court compel production of documents "related to" the ICM should be denied.

D. RIIiO Pilot Study

Finally, Plaintiffs complain that Defendants have not supplemented their production to include more recent documents concerning the RIIiO pilot study being conducted by independent investigators in the United Kingdom. (Defendants did produce study protocols and other related documents during the general causation phase.) Plaintiffs fail, however, to articulate how those documents would be relevant to the litigation. While 3M provided partial funding for the RIIiO pilot study, 3M is not conducting the pilot study itself and has no non-public information about the results. Nor is 3M relying on the results of the pilot study at this time, for the simple reason that no results have been disclosed by the researchers. There is nothing relevant to this litigation about a pilot study that has not yet reported any results.

The status of the ongoing pilot study is also no secret. 3M has provided Web links to the information that the study authors have been posting online about the study, and Plaintiffs have cited those links at footnote 118 of their Memorandum.

Plaintiffs allege "on information and belief" that 3M "declined to continue funding the remainder of this randomly controlled [sic] clinical trial." On the contrary, 3M agreed to fund $100,000 of the cost of the pilot study over two years, and it fulfilled that commitment. 3M never committed to fund a subsequent study. Even if Plaintiffs were correct that 3M "declined to continue funding the remainder" of the study (and they are not, and one must wonder the basis for Plaintiffs' purported "information and belief," Pl.

Mem. at 26), it still would be irrelevant to Plaintiffs' claims. 3M's partial funding of an ongoing pilot study does not make it more probable that the Bair Hugger system was defectively designed when delivered to Plaintiffs' hospitals, that the Bair Hugger system caused their alleged injuries, or that Defendants failed to warn hospitals of a known risk. Those are the fighting issues in this litigation.

For these reasons, Plaintiffs' motion to compel production of documents relating to the RIIiO pilot study should also be denied. If and when the results of the RIIiO pilot study are made available, and the parties have been able to determine whether the results have any relevance to the litigation and whether they will rely on them, Defendants are willing to meet-and-confer with Plaintiffs and respond to relevant discovery, as they did following the FDA's release of its August 2017 letter. Defendants will also continue to fulfill their duty to identify or produce documents that they may use to support their defenses at trial, as provided by Fed. R. Civ. P. 26(a)(1)(A) and 26(e)(1)(A).

II. PLAINTIFFS FAIL TO DEMONSTRATE GOOD CAUSE FOR REOPENING GENERAL CAUSATION DISCOVERY.

Beyond these three specific areas, Plaintiffs request in a footnote that the Court issue an order that "discovery responses be supplemented broadly." Pl. Mem. at 1 n.1. Plaintiffs' position seems to be that Defendants have a general obligation to supplement production in response to every one of the 200+ document requests and 30 interrogatories served in the general causation phase of the MDL.

The Federal Rules do not support such an expansive duty to supplement – really, a wholesale reopening of general causation discovery. Fed. R. Civ. P. 26(e)(1)(A) requires a

party to supplement only "if the party learns that in some material respect the disclosure or response is incomplete or incorrect, and if the additional or corrective information has not otherwise been made known to the other parties during the discovery process or in writing." Plaintiffs do not cite any case holding that a party has an obligation to continuously "refresh" its production after the close of discovery other than the obligation imposed by that Rule.[4] Beyond the three issues discussed above, Plaintiffs identify no other respects in which Defendants' general causation discovery responses are allegedly incomplete or incorrect, and Defendants are not aware of any.

Moreover, Fed. R. Civ. P. 26(b)(1) limits the scope of discovery to nonprivileged matters "relevant to any part's claim or defense and proportional to the needs of the case." Over the course of the last three years, the Court's many rulings on discovery issues, admissibility, and other issues have considerably narrowed the scope of what is discoverable. For example, Plaintiffs' discovery requests in the general causation phase were heavily geared toward supporting a possible claim for punitive damages, but following the close of discovery the Court denied Plaintiffs' motion for leave to amend. In short, what might be relevant today is considerably narrower than what might have been relevant prior to the Court's rulings. The burden of requiring Defendants to comprehensively refresh their production on all subjects of discovery would far outweigh any possible benefit. Fed. R. Civ. P. 26(b)(1).

[4] Indeed, most case law addressing the duty to supplement involves sandbagging – a party's improper attempt to use evidence at trial that it should have disclosed much earlier. *See, e.g.*, *Transclean v. Bridgewood Servs., Inc.*, 101 F. Supp. 2d 788, 795 (D. Minn. 2000).

Due to the limited scope of the duty to supplement, Plaintiffs' broad demand is clearly a request to reopen general causation discovery. Reopening general causation discovery now, when the parties are in the bellwether phase would (as the Court said in affirming the exclusion of Plaintiffs' supplemental general causation expert reports) "undermine the efficiency of the MDL and the purpose behind bifurcating discovery." Dkt. No. 1580, Order. Moreover, such a request must be supported by good cause, Fed. R. Civ. P. 16(b)(4), which Plaintiffs have failed to demonstrate here. The words "good cause" never even appear in their Memorandum.

In addition, Plaintiffs' demand for a comprehensive "refresh" of Defendants' production ignores the lengthy history of the parties' discovery negotiations and the Court's rulings. Through many days of meet-and-confers, the parties narrowed or set aside many of Plaintiffs' requests. The Court formally and informally resolved many disputes, including declining Plaintiffs' request for production of customer lists. Dkt. No. 121, Court Minutes. Ultimately, the parties narrowed their disputes to whether Defendants should be required to search additional custodians beyond a group of 26. Hulse Decl. Ex. C., 8/18/16 Status Conf. Tr. at 50:2-9 ("MAGISTRATE JUDGE NOEL: Okay. Let me just make sure I understood what you just told me. If there is a resolution of this issue regarding custodians, and I'm not sure I fully understand exactly how that issue would be framed. But if that issue is resolved, most of these 90-plus line items in the chart [of discovery disputes] would go away? MS. ZIMMERMAN: I think that's correct, Your Honor."). Following briefing and argument, the Court concluded that the search of 26 custodians was sufficient. Dkt. No. 109, Order. Yet Plaintiffs make no reference to this history and fail to explain

(beyond the three subjects addressed above) how they believe Defendants' responses to their specific discovery requests, as narrowed by agreement and Court orders, needed to be supplemented.

In sum, Plaintiffs offer no viable legal or factual basis, much less good cause, to reopen general causation discovery and impose a broad, undefined obligation on Defendants to refresh their general causation production.

CONCLUSION

For all the foregoing reasons, Defendants respectfully request that this Court deny Plaintiffs' motion to compel. Plaintiffs have not shown that Defendants' production is incomplete or incorrect in any material respect, much less that there is good cause to broadly reopen general causation discovery. To the extent the Court nonetheless concludes that general causation discovery needs to be "refreshed," however, it should be done in an orderly and considered manner, with a focus on the issues that are still relevant to the litigation considering the Court's discovery, evidentiary, and legal rulings. Any obligation should apply to all parties, not just Defendants, and should address the failure of dozens of Plaintiffs' firms to ever serve general causation discovery responses in the first place.

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Respectfully submitted,

s/Benjamin W. Hulse

Jerry W. Blackwell (MN #186867)
Benjamin W. Hulse (MN #0390952)
Mary S. Young (MN #0392781)
BLACKWELL BURKE P.A.
431 South Seventh Street, Suite 2500
Minneapolis, MN 55415
Phone: (612) 343-3200
Fax: (612) 343-3205
Email: blackwell@blackwellburke.com
bhulse@blackwellburke.com
myoung@blackwellburke.com

Lyn Peeples Pruitt
MITCHELL WILLIAMS SELIG
GATES & WOODYARD
425 West Capitol Avenue, Suite 1800
Little Rock, AR 72201-3525
Phone: (501) 688-8869
Fax: (501) 688-8807
Email: lpruitt@mwlaw.com

Bridget M. Ahmann (MN #016611x)
FAEGRE BAKER DANIELS LLP
2200 Wells Fargo Center
90 South Seventh Street
Minneapolis, MN 55402
Phone: (612) 766-7000
Email: bridget.ahmann@faegrebd.com

Counsel for Defendants 3M Company and Arizant Healthcare Inc.